UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,843	02/20/2004	Munetetsu Tei	249212US0CONT	4144

22850 7590 12/08/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,843	TEI, MUNETETSU	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *7-18 and 28-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 19-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/082,082.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, in the reply filed 5/25/05 is acknowledged. The traversal was addressed, and the restriction made final, in the supplemental restriction requirement issued 8/9/05. Applicant's further election of the species Rauwolfia serpentine, without traverse, in the reply filed on 9/8/05 is acknowledged. Claims 37-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Additionally, Claims 7-18 and 28-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6 and 19-27 read on the elected invention and are being acted upon.

2. Claims 22-27 are objected to because of the following informalities:

The Latin names of plants or other biological materials should be italicized. Appropriate correction is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to an antitumor/antiviral medication that is made by inducing heat shock proteins in lymphocytes by heating and/or culturing with galenical extracts (i.e. they are drawn to a product by process of making). However, the process of making does not indicate what the final product comprises. For example, the antitumor/antiviral medication may be an activated lymphocyte, a heat shock protein,

a galenical extract, or combinations thereof. Hence, the claims as written are indefinite.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, Applicant has not adequately disclosed that they are in possession of the claimed genus of "galenical extract"

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, §1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly*

and Co. 43 USPQ2d 1398.

Galenical extract is the recitation of a broad genus for which Applicant has only disclosed a limited number of species, *Rauwolfia serpentine, Linderae radix, Safflower* extract, and *Scutellariae radix*. The instant specification does not correlate the functional characteristics of galenical extracts with any structural characteristics. Therefore, no estimation can be made of the characteristics, structures, or other physical or chemical properties of the genus of galenical extracts. Webster's dictionary defines "galenical" as a medicinal preparation composed mainly of herbal or vegetable matter. Therefore, a "galenical extract" might encompass various herbal remedies such as ginseng, chamomile, or garlic that do not have any known ability to induce heat shock proteins. Also, said extract might be obtained by water, alcohol, or oil extraction, which would "extract" different compounds. For example, reserpine, the active ingredient of *Rauwolfia serpentine* is not water soluble (see Report on Carcinogens, 11th Edition). Thus, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the broad genus of galenical extracts that would function to generate the medication of the instant claims

6. Claims 1-6 and 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification provides insufficient guidance to make the invention as broadly claimed, and also provides insufficient evidence that the claimed invention could function as an antitumor/antiviral medication.

The specification disclosure is insufficient to enable one skilled in the art to make and use the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of

experimentation needed to make or use the invention, *in re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

With regards to the instant claims, the specification provides insufficient guidance to enable claims drawn to the antitumor/antiviral medication as broadly claimed. Note that a product claimed as an antitumor/antiviral medication must be enabled as a medication that is useful for treating cancer and viral infections. The medication of the instant application comprises lymphocytes that have been induced to express heat shock proteins by heating and/or culturing with galenical extracts. A "galenical extract" might encompass various herbal remedies such as ginseng, chamomile, or garlic. Additionally, the process by which said "extracts" are made might comprise water, alcohol, or oil extraction, which would "extract" different compounds. For example, reserpine, the active ingredient of *Rauwolfia serpentine* is not water soluble (see Report on Carcinogens, 11th Edition). Therefore, it is apparent that the process of producing the lymphocytes encompasses culturing with reagents that do not have a known ability to induce heat shock proteins (for example, garlic or water extracts of *Rauwolfia serpentine*). Thus, one of skill in the art is not enabled to make the invention as broadly claimed.

Furthermore, it is known in the art that both heating and reserpine treatment results in decreased functional capacity of

lymphocytes, as measured by reduced ability to proliferate (see Kamwanja, table 2, and Mekori, Fig. 1). It is also well known in the art that a main effector mechanism in the control of tumors and viral infections are cytotoxic T lymphocytes (see Ochsenbein, pg. 1043, and Nabel, pg. 1945). Thus, given the state of the art, it is unclear how administration of suppressed lymphocytes would be beneficial for treating tumors or virus infection. Therefore, the instant specification must provide sufficient guidance, generally in the form of data, that would enable a medication comprising said lymphocytes for treating tumors or virus infection. However, the instant specification does not provide any evidence that lymphocytes in which heat shock proteins have been induced are beneficial for treating tumors or virus infection. The only working example provided in the instant specification involves injecting reserpine and heat treated lymphocytes into tumor bearing mice, which results in a modest survival benefit. Note that the instant claims only recite the use of reserpine in culture to induce heat shock proteins in lymphocytes. The claims do not require that the medication contains reserpine. Thus, this specific example involving a rodent tumor model does not provide sufficient support, i.e. is not commensurate in scope, with the antitumor/antiviral medication as claimed. Accordingly, the instant medication comprises only an idea and not an invention. Therefore, the medication as claimed must be considered highly unpredictable. Given said unpredictability, the medication of the instant claims must be considered to require undue experimentation for use as a treatment for tumors or viral infection.

7. It is noted that that for the purposes of prior art, the instant invention is being interpreted as a medication comprising activated lymphocytes expressing heat shock proteins.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-6 and 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamwanja et al., 1994, J. Anim. Sci.

Kamwanja teaches a composition of PHA activated lymphocytes in which heat shock protein 70 (HSP70) has been induced by heating at 42 degrees Celsius for 12 h (see pg. 440 and 441). The instant claims are drawn to a antitumor/antiviral medication produced by activating lymphocytes and inducing heat shock proteins. This can be interpreted to mean a medication comprising said lymphocytes. The recitation of antitumor/antiviral medication has not been given any patentable weight, since it refers to an intended use of the composition of activated lymphocytes. "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See also MPEP § 2112. Furthermore, it is noted that claims 19-27 recite a process of producing activated lymphocytes in which heat shock proteins have been induced using *Rauwolfia serpentina*/reserpine. However, the instant claims are drawn to a product (activated lymphocytes), and the patentability of the product does not depend on its method of production.

Thus, the reference clearly anticipates the invention.

10. Claims 1-6 and 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Jin et al., 2000, Biotherapy.

Jin teaches a composition comprising activated T lymphocytes in which HSP70 has been induced by a combination of heating to 42 degrees Celsius and reserpine culture (see abstract and Fig. 1).

Thus, the reference clearly anticipates the invention.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600
October 27, 2005

11/22/05
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER